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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/662,216

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EXAMINER

LANG, AMY T

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/662,216	Applicant(s) PAVCNIK ET AL.	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/07/2004, 12/08/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner would like to point out that claim 40 was erroneously not included in the restriction requirement. Since claim 40 is drawn to a filter apparatus, it is therefore is appropriate for group I of the restriction requirement.

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-40, in the reply filed on 03/14/2008 is acknowledged.
2. Claims 41-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/14/2008.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the z-stent must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claim 21** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 recites wherein the stent is balloon expandable. However, the instant specification does not support this limitation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1-6, 8-16, 19, 20, 24-26, and 30-36** are rejected under 35 U.S.C. 102(e) as being anticipated by Goldberg et al. (US 2002/0116024 A1).

With regard to **claim 1**, Goldberg et al. (hereinafter Goldberg) discloses a retrievable filter comprising a filter (10) and a stent (100) ([0041]). Tethers (14a-14c) on the filter are attached to hinges (24) on the stent to form a releasable locking mechanism (Figure 4; [0045]; [0060]).

With regard to **claim 2**, the tethers overlap the instantly claimed stent attachment means and the hinges (24) overlap the filter attachment means.

With regard to **claim 3**, the stent is configured to engage a wall of a patient's vessel ([0001]).

With regard to **claim 4**, as shown in Figure 1, the filter comprises an apical hub (24).

With regard to **claims 5 and 6**, the filter comprises a plurality of divergent legs (12a-12c and 16a-16c) ([0041]; [0046]). As shown in Figure 5, at least one leg is secured

at one end to the apical hub (24). At the other end, the leg is releasably secured to the stent (100) by the locking mechanism.

With regard to **claim 8**, Goldberg further discloses hooks (130a-130c) that provide a retention force (Figure 1; [0058]). Apical hub (24) provides a retrieval force that allows the filter to detach from the stent ([0054]).

With regard to **claims 9 and 10**, since the filter comprises Nitinol, it is the examiner's position that the filter is configured to maintain its structure when detached from the stent (0042]).

With regard to **claims 11-15**, as shown in Figure 6, the filter avoids contact with a patient's vessel when placed within the vessel.

With regard to **claims 16 and 17**, it is the examiner's position that the locking mechanism is further configured to avoid contact when placed in a patient's vessel.

With regard to **claim 19**, as shown in Figure 1, the stent (110) comprises a z-stent.

With regard to **claim 20**, Goldberg further discloses the stent as comprised of Nitinol, which clearly overlaps the instantly claimed self-expanding ([0055]).

With regard to **claims 24-26 and 30-35**, the tethers (14) and hinges (24) comprising the releasable locking mechanism are formed of wire, which clearly overlaps the instantly claimed attachment wire. As shown in Figures 1 and 3, both the tethers and hinges are bent and the hinges additionally comprise a coiled, looped wire.

With regard to claim 36, it is the examiner's position that the filter is configured so that a user can decrease the force required to detach the filter from the stent ([0054]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 16-18 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (US 2002/0116024 A1).

Goldberg discloses a retrievable filter comprising a filter, a stent, and a locking mechanism between the filter and stent.

With regard to **claims 16 and 17**, if Applicant were to argue that the locking mechanism of Goldberg is not configured to avoid contact with a patient's vessel, it is the examiner's position that such would involve a mere change in the angle of the stent. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to alter the angle from which the stent extends from the filter because Applicant has not disclosed that altering the angle provides an advantage, is used for a particular purpose or solves a stated problem. One

of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stent angle of Goldberg because both filters are able to effectively trap emboli.

With regard to **claim 18**, although Goldberg does not specifically disclose the stent as square, it is the examiner's position that such a change in shape is obvious to one of ordinary skill in the art. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the shape of the Goldberg stent because Applicant has not disclosed that a square stent provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the cylindrical stent of Goldberg because both filters are able to effectively trap emboli.

With regard to **claim 21**, although Goldberg does not specifically disclose the stent as balloon expandable, it is the examiner's position that balloon expandable stents are well known to one of ordinary skill in the art. Therefore, it would have been obvious at the time of the invention to one of ordinary skill in the art for the stent of Goldberg to be balloon expandable.

11. **Claims 2, 5-7, 22, 23, 24, 27-29, and 37-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (US 2002/0116024 A1) as applied to claim 1 above, and further in view of DeVries et al. (US 6,342,063 B1).

Goldberg discloses a retrievable filter comprising a filter, a stent, and a locking mechanism between the filter and stent. However, Goldberg does not specifically

disclose the locking mechanism comprising an interference fit, cannula, slot and ball, or Y-shaped adaptor.

DeVries et al. (hereinafter DeVries) also discloses a retrievable filter (Figure 1). As shown in Figures 2 through 5, DeVries discloses a locking mechanism between a filter leg and an anchoring portion. This locking mechanism comprises a cannula (38) or a link connecting the two components. Since DeVries discloses a locking mechanism between a filter leg and an anchoring mechanism, which acts similar to a stent, it would have been obvious to one of ordinary skill in the art for Goldberg to also utilize the same locking mechanism.

Other links such as an interference fit, slot and ball, and Y-shaped adaptor are well known to one of ordinary skill in the art. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the filter. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Therefore, it would have been obvious to one of ordinary skill in the art for Goldberg in view of DeVries to utilize a locking mechanism comprising an interference fit, cannula, slot and ball, or a Y-shaped adaptor, absent evidence to the contrary.

With regard to **claim 37**, Goldberg further discloses a hook (40) attached to the apical hub (24) (Figure 2). The hook is connected to locking ring (38) on the apical hub (Figure 2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

05/22/2008
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